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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT PAPER NUMBER

1655

DATE MAILED: 12/21/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/591,466

Applicant(s)

SCHAEWEN, ANTJE VON

Examiner

Jeanine A Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3 and 31-48 is/are pending in the application.
- 4a) Of the above claim(s) 41-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,31-40,47 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, and *Solanum tuberosum* in Paper No. 16 is acknowledged.

Applicant's traverse the restriction requirement. Applicant's assert that a search of Groups I, II and V would not be a burden and is requested. Examiner has rejoined these three groups as requested by the applicant. A search of Claims 2-3, 31-40, and 47-48 has been performed to the extent that they read on SEQ ID NO: 1. Claims 41-46 remain drawn to non-elected subject matter.

Applicant's further traverse the restriction to a single nucleotide sequences. Since SEQ ID NO: 1, 3, and 5 do not encode the same protein, it appears as though applicant is arguing Applicant's cite the O.G. notice from 1996 which provides that "up to 10" sequences will be examined. First, the O.G. notice was designed for specific sequences which little is known about the sequences such as ESTs. Secondly, the O.G. notice is permissive of a search of 10 sequences, the notice does not require a search of 10 sequences. Since applicant has not indicated that the sequences presented are not patentably distinct, restriction to a single sequence is appropriate.

Prior to allowance, applicant must cancel non-elected subject matter.

Priority

2. This application claims priority to PCT EP98/08001, filed December 1998 and foreign document 197 54 622.6, filed December 9, 1997.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Sequence Rules

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

A) Figure 2 and 3b contain sequence listings which are not identified by SEQ ID NO.

B) On page 31, 32 for example, numerous primers are provided which are not identified by SEQ ID NO: .

Appropriate correction is required.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2, 31-35, 37, 39, 47-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any plant *N-acetylglucosaminyltransferase I*.

The specification teaches SEQ ID NO: 1, 3, 5 which are nucleic acid molecules asserted to be *N-acetylglucosaminyltransferase I* from tobacco, potato and Arabidopsis.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2b 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed”. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2b 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA...’ required a precise definition, such as by structure, formula, chemical name, or physical properties’, not a

mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, Applicant has defined only three nucleic acid sequences within the scope of the claimed genus. It is unclear what the structure of plant *N-acetylglucosaminyltransferase I* are such that one of skill in the art may obtain a plant GnT I sequence or a potato GnT I sequence.

First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are directed methods which utilize N-acetyl glucosaminyl transferase I polynucleotides. With regard to the elected invention, the specification only describes a single protein and a single cDNA encoding that protein and fails to teach or describe any other polynucleotides that are related to SEQ ID NO: 1 within the limitations of the rejected claims. The specification provides no guidance as to how or where the disclosed polynucleotide can be modified yet still maintain the functionality required for the instant methods. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or

functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention.

With respect to the *Solanum tuberosum* nucleic acids, applicant's have provided the description of a single species. Applicant's have not provided how to identify that a *N-acetylglucosaminyltransferase I* sequence is from potato origin as opposed to tobacco or *Arabidopsis* origin or additionally other origins. While applicant's may be entitled to homology language with functional language, Applicant's have not described *Solanum tuberosum* nucleic acids encoding *N-acetylglucosaminyltransferase I*.

With respect to the hybridize under stringent conditions in part c of Claim 35, the claim is sufficiently broad such that the claim does not have a structure function relationship such that any nucleic acid which would hybridize under stringent conditions would be encompassed. Stringent conditions are defined on page 10 of the specification. These nucleic acids have not been either described nor enabled. Amendment of Claim 35 to encompass the limitations of Claim 36 would overcome the rejection since the claim would have both a structure and function relationship.

In the application at the time of filing, there is no record or description which would demonstrate conception or written description of any plant or potato *N-acetylglucosaminyl transferase* polynucleotide.

Claim Rejections - 35 USC § 112-Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2-3, 31-34, 37-40, 47-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing glycoproteins which contain minimal Man5GlcNAc2 by transforming plants, plant cells or parts of plants with sense SEQ ID NO: 1 which encodes an *Solanum N-acetylglucosaminyltransferase I* and isolating the desired glycoprotine from the cultivated material, plants comprising the sense SEQ ID NO: 1 which encodes a *Solanum N-acetylglucosaminyltransferase I*, does not reasonably provide enablement for a method of producing glycoproteins with contain minimal Man4GlcNAc2 using the antisense construct of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

It is noted that with regard to specific sequences, a restriction requirement was set forth, and applicant elected methods which utilize SEQ ID NO: 1. The generic claims have been examined fully, and the claims which specifically recite multiple inventions have been examined insofar as they apply to the elected invention.

The claims are broadly drawn to methods of producing glycoproteins which contain minimal Man5GlcNAc2 by transforming plants, plant cells or parts of plants with sense or antisense of SEQ ID NO: 1 which encodes an *Solanum N-*

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erases comprising the sense or antisense SEQ ID NO: 1 which encode *N-acetylglucosaminyltransferase I*.

the human *N-acetylglucosaminyltransferase I* is 35% identical to the potato gene. The specification teaches transforming the binary

construct (SEQ ID NO: 1) *GnTI* constructs into *Agrobacterium* and into the tobacco plants. The specification provides that the antisense complex glycoproteins was successful in the potato plant #439 (page 35,

the specification teaches a method of producing glycoproteins by cultivating mutant plant

cells encoding human *N-acetylglucosaminyltransferase I* which restores the

wild-type phenotype of the plant cells (Gomez, PNAS, 1994, abstract). Gomez teaches that the *cgl* mutant of *Arabidopsis* lacks *GnT I* was cultured with cDNA encoding the human *GnT I* which restores the wild-type phenotype. The art teaches an assay for *GnTI* (page 1830, col. 2).

Thus, Neither the specification nor the art teaches how to make and use the invention as broadly as claimed. As noted above, the specification has only described three *N-acetylglucosaminyltransferase I* genes. This does not enable the skilled artisan to make additional sequences (see Description rejection above).

Moreover, while the art teaches that the sense human *N-acetylglucosaminyltransferase I* restores the wild-type phenotype of the plants cells, the art is silent with respect to the use of the antisense construct. The instant specification

illustrates that the antisense construct suppresses the expression of GnTI. Thus, it is unclear what the antisense construct may be used for. While restoring wild-type activity is useful for the processing of the glycoproteins, it is unclear what the generation of the mutant comprising the antisense may be useful for. The claims which are directed to producing glycoproteins with minimal GluNAc2Man5 do not appear to be enabled for use with antisense constructs. From the data in the specification antisense constructs appear to block expression such that complex glycan are not synthesized yielding large quantities of the GlucNAc2Man5.

Moreover, it is noted that the instant claims encompass methods which utilize nucleic acids that are related to SEQ ID NO: 1 based on hybridization. However, Applicant provides no guidance for the regions of the disclosed gene *N-acetylglucosaminyltransferase I* which are essential or sufficient to encode *N-acetylglucosaminyltransferase I*, or for the regions of SEQ ID NO: 1 which are essential or sufficient to encode a *N-acetylglucosaminyltransferase I*. In the absence of such guidance, undue trial and error experimentation would be required to screen for additional plant *N-acetylglucosaminyltransferase I* genes.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2-3, 31-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 2-3, 31-34 are indefinite over the recitation "minimal, uniform GlucNac2Man5-residues". The term "minimal" in claim 31 is a relative term which renders the claim indefinite. The term "minimal" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Further Claim 31 is confusing. It is unclear based upon the instant claim language the limitations of Claim 31. It is unclear which phrases are modifying which limitations. Consolidation of the related limitations or simplification of the claim would provide a clearer claim.

B) Claims 32-34 are indefinite. It is unclear what the limitations of Claim 32 and 33 are intended to encompass. Claim 32-33 are directed to using the gene encoding the desired glycoprotein, however, based upon Claim 31, it appears as though the claim had required the use of a *N-acetylglucosaminyltransferase I*. Clarification of Claim 31 may illustrate the differences in the claims, however, currently, it is unclear how Claims 32 and 33 limit Claim 31.

C) Claim 47-48 are indefinite because it is unclear how all of the elements of the claim are related. It is unclear what "an extrachromosomal propagation and transcription of the antisense construct in the plant tissue infected" is intended to modify. Further, "obtainable by integration of one or more antisense or sense DNA of claim 35 under the

control of a promoter effective in plants, into the genome of a plant or by viral infection..." It is unclear what is the alternative, the promoter or by viral infection.

Claims 47-48 are confusing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Gomez et al (PNAS, Vol. 91, pages 1829-1833, March 1994).

Based upon the broad language of the claim which recites a sequence comprising part of a plant *N-acetylglucosaminyltransferase I* the claims have been read to encompass any part of a plant gene, such that the part, one nucleotide, may be embedded within a larger sequence, namely the human *N-acetylglucosaminyltransferase I* gene.

Gomez teaches a method of producing glycoproteins by cultivating mutant plant cells with cDNA encoding human *N-acetylglucosaminyltransferase I* which restores the wild-type phenotype of the plant cells (abstract). Gomez teaches that the cgl mutant of

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Arabidopsis lacks GnT I was cultured with cDNA encoding the human GnT I which restores the wild-type phenotype. Thus, since Gomez has taught every limitation of the claimed invention, Gomez anticipates the instant claims.


Conclusion


8. No claims allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Enewold Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday, Wednesday and Friday 7:00 a.m. to 5:30 p.m. and Tuesday and Thursday from 7:00 a.m. to 1:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Enewold Goldberg
December 19, 2001 


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1800